EXHIBIT C

IN RE: England v. Ethicon

THIS DOCUMENT RELATES TO The case of England v. Ethicon

EXPERT REPORT OF DR. LENNOX HOYTE

The following report is provided pursuant to my review of pertinent records for Theresa England. All of the opinions that I offer in this Report I hold to reasonable degree of medical or scientific certainty.

1.

I am a female pelvic surgeon, formally trained in Female Pelvic Medicine and Reconstructive Surgery(FPMRS). I have personally trained fellows in my board approved FPMRS fellowship training program in Tampa, and also trained many residents in pelvic surgery techniques between 2005 and 2015, when I was founding director of the FPMRS fellowship program at the USF College of Medicine. I served on the faculty of OB/Gyn at Harvard Medical School – Brigham and Womens' Hospital in Boston, and started the division of Female Pelvic Medicine and reconstructive surgery at the USF Morsani College of Medicine in Tampa, Florida, where I served as Professor and Fellowship Director of the FPMRS program from 2006, until I left the University to start a private surgical practice in 2016. I also pioneered the field of MR based three-dimensional reconstruction of the female pelvic floor organs, and published many original peer-reviewed manuscripts in the area of 3D female pelvic floor anatomy. My Curriculum Vitae is attached as **Exhibit 1**. I personally perform about 350 pelvic surgical procedures annually, including robotic, open, and transvaginal procedures to address pelvic organ prolapse, urinary

and fecal incontinence, bladder and bowel control problems. I have personally performed over 1300 synthetic large-pore polypropylene retropubic sling procedures, over 500 Autologous Rectus Fascial (ARF) sling procedures, over 1500 sacrocolpopexies, and hundreds of native tissue prolapse repairs via vaginal and robotic laparoscopic routes. I have also explanted over 800 transvaginal mesh products via vaginal and laparoscopic robotic routes.

About fifty of the surgeries I currently perform annually are for the removal and/or revision of transvaginally placed mesh, due to complications like mesh related pain, dyspareunia, hyspareunia, erosion, extrusion, exposure, abscess formation, perforation of visceral organs, urinary retention, bowel and bladder dysfunction. I have personally explanted over 800 trans-vaginal mesh and sling products due to complications. From my personal experience with over three thousand female pelvic floor related surgeries, and my experience in training fellows and residents in pelvic surgery, it is my professional medical opinion that pelvic floor surgery is a skill to be painstakingly learned and products for pelvic floor repair cannot be universally marketed to all surgeons. I have never been a proponent of trocar-based transvaginally implanted mesh for pelvic organ prolapse repair, and I have never been a proponent of trans-obturator slings for stress urinary incontinence.

Approximately in 2002, when I served as a generalist OB/Gyn physician in Boston, I was approached by an engineer from Johnson and Johnson regarding my research in MR-based 3D pelvic reconstruction. As I recall, the engineer asked if I was interested in building 3D models to help understand the anatomy of the pelvic

floor related to pelvic reconstructive surgery. I opted not to follow up on the request, due to my other professional commitments. In the past, I have also attended sponsored cadaver training sessions, and was under consulting contracts with AMS and Bard Urological. In the past 10 years, I have also served as laboratory faculty for 2 cadaver dissection courses, one for Boston Scientific, and the other for Coloplast. I did not teach any transvaginal prolapse mesh placement techniques for either of these laboratory courses. I have also served as a surgical proctor for Intuitive Surgical, also giving lectures and running cadaver lab trainings to teach robotic sacrocolpopexy techniques. I have never taught transvaginal mesh placement techniques for prolapse repair or transobturator slings.

The only mesh procedures that I perform are abdominal (open and robotic) sacrocolpopexies, and the only types of incontinence slings that I place are large pore, low stiffness retropubic slings. I also place autologous fascial slings for women with stress urinary incontinence, who either refuse polypropylene implants, or have had exposures or erosion of previously implanted polypropylene mesh. I have never implanted a trans-obturator sling in a living woman, because of my belief that the transobturator approach requires sling passage through, and scarring into the levator, obturator, and adductor muscles, causing pain and irritative bladder symptoms during and after the healing process. I use the retropubic approach because sling passage is via the space of Retzius, and anchoring is through the tendons of the rectus abdominis muscles near the symphysis: in my experience, inevitable mesh shrinkage of up to 50%, and scarring into these tendons do not cause long term, chronic postoperative pain. In addition, with the large pore, low-

stiffness polypropylene retropubic sling, only a very small amount of synthetic mesh remains in direct contact with the vaginal wall, minimizing the size of the vaginal scar, minimizing the risk for scar pain and mesh exposure. Furthermore, I exclusively use large pore polypropylene slings, which come enclosed in plastic sheaths, designed to protect the sling material from the vaginal fluids and bacteria during placement, and also protect the pelvic tissues from friction of the polypropylene material during initial sling placement. The protective sheaths are removed after the sling is placed in its final position. Another reason that I use the retropubic pathway is that retropubic sling tension can be re-adjusted long after implantation via the space of Retzius, using endoscopic techniques.

I routinely follow all of my mesh-implanted patients annually with detailed pelvic examinations and symptom review. In my personal experience with placing approximately 1300 of the large pore, sheathed retropubic slings over the past 14 years, I have seen less than 10 cases where the retropubic sling eroded into the vagina or viscera.

I have never placed a kit-based transvaginal mesh for prolapse repair from any manufacturer, in any living patient, at any time. I have never been a proponent of trocar-based transvaginally implanted mesh for pelvic organ prolapse repair.

I currently place retropubic synthetic mesh slings for stress urinary incontinence, and have done so for over 14 years. I also perform autologous fascial sacrocolpopexy and autologous fascial retropubic sling procedures, in addition to other native tissue repairs, like anterior/posterior repairs, sacrospinous fixations, and uterosacral suspensions via vaginal and laparoscopic routes. I have never

placed a transvaginal synthetic sling from any manufacturer, in a living patient via the trans-obturator route.

I have also personally removed over 800 transvaginal mesh implants, including at least 200 transobturator slings, so determined from patient accounts, surgical operative notes and operating room determination of the sling path.

In my extensive personal experience with managing complications from anti-incontinence procedures, the main reasons for explanting transobturator slings is because of pain, pain with intercourse, groin pain, mesh exposure, as well as defecatory dysfunction, and the main reason for removing retropubic slings is mesh erosion into the vagina, urethra, or bladder. In my surgical practice, I have developed techniques for adjusting retropubic slings in case of urinary retention, and postoperative stress incontinence, and these therapies make retropubic sling removal unnecessary in cases of retention or persistent stress incontinence.

I have reviewed Instructions for Use ("IFUs") for Implanted products that I use throughout my career.

I have reviewed the general and product specific literature related to the Gynecare TVT-O and Prolift products.

This, together with my substantial training and experience in Engineering, FPMRS, female pelvic surgery, and anatomy, gives me adequate experience to offer opinions about the Gynecare TVT-Obturator and Gynecare Prolift mesh products.

Prolift METHOD OF IMPLANTATION

The Gynecare Prolift and Prolift +M systems require transvaginal implantation of a synthetic polypropylene mesh using specially designed trocars (needles) and sleeves. These products are comprised of a main mesh area, and four arms (Prolift, Prolift+M), which act as fixation points to anchor the mesh arms in the obturator internus, levator ani muscles, and the sacrospinous-coccygeus complexes bilaterally. The Prolift and Prolift+M products consist of a central portion with four arms for anchoring the mesh in the pelvic sidewall, and are sold as separate systems intended for the independent treatment of anterior and posterior prolapse.

The arms are passed through the sacrospinous-coccygeus complex proximally and through the obturator foramen, and near the junction of the superior and inferior pubic rami distally. The products are implanted by blindly passing plastic-sleeved trocars inward through the perineal skin, obturator foramen, obturator internus, levator ani or sacrospinous-coccygeus complex, out through a mid-vaginal incision, then withdrawing the trocars and leaving the plastic sleeves in place. A noose is then passed through each plastic sleeve, and brought into the midvaginal incision. Then, the mesh arms are placed into the loop of each noose, which is then pulled out to bring each mesh arm outward into place, thereby anchoring the mid portion of the mesh between the bladder and anterior vaginal wall. The inner diameter of the Prolift plastic sleeves is 3.7 millimeters, and the width of the Prolift mesh arms are 20 millimeters. As the Prolift mesh arms are being pulled through the plastic sleeves, they are placed on tension, and have to squeeze and must bunch up to fit in the smaller cylindrical sleeves, which causes deformation and curling of the arms, altering the shape of the arms at the point of

contact with the pelvic sidewall, and importantly shrinking of the pore size of the mesh arms, compared to the pore size at rest. Shrinkage of the pores will make it difficult for the surrounding tissues to integrate into the mesh during healing, and this causes a painful, scar plate to develop. The arms are composed of synthetic polypropylene mesh, and they are intended to scar into place at the muscle attachment points for each arm. For the anterior Prolift products, there will be two arms in the left pelvic sidewall muscles (the sacrospinous-coccygeus complex proximally, and the obturator internus and levator ani distally), and the other two arms in the right pelvic sidewall muscles. In this way, the main body of the Prolift mesh is intended to support the anterior wall of the vagina, in an attempt to correct anterior prolapse.

When the transvaginal mesh shrinks during the normal healing process, the arms of the mesh pull on their anchoring points in the pelvic sidewall muscles (obturator, sacrospinous-coccygeus, and levator ani), tending to pull these anchoring points and the attached muscle toward the midline. It is my opinion that, in women with these transvaginal mesh implants, this pulling on the pelvic sidewall muscles causes pain; at rest, during sexual intercourse, during defecation, and during normal daily activities like coughing, jumping, and straining. Attempts at defecation or sexual penetration will push on the mesh, aggravating the pulling on the arms as stool attempts to come out of the rectum, or as a vaginal insert (i.e., penis) is placed into the vagina during intercourse. This aggravated pulling will cause new or worsening pain to the women in whom the product is implanted. Furthermore, this “side –to-side” surgical approach attempts to address apical

(upper end of the vagina) prolapse that may be present by anchoring the mesh arms bilaterally through the sacrospinous-coccygeus complex. However, this bilateral spanning anchoring creates a nonexpandable "spanning" bridge over the rectum which has the potential to obstruct stool passage and cause pain with defecation. During coughing, jumping, or straining down, pressure is placed on the mesh, which is transmitted to the attachments in the pelvic sidewall, also deforming and pulling on the muscle at the attachment points. Additionally, transvaginal mesh is passed into position through the vagina, and is exposed to the "clean-contaminated" vaginal microbial environment as it is being put into position. Despite intensive antimicrobial preparation, the "clean-contaminated" environment of the vagina presents an opportunity to contaminate the mesh as it is being passed into position through the vagina.

I perform abdominal sacrocolpopexy (hereinafter ASC) procedures using abdominally placed mesh. The ASC procedure is designed to address apical, anterior, and posterior, prolapse. The ASC uses a "Y" shaped mesh to lift the vaginal apex, anterior, and posterior walls to a position inside the pelvic cavity, by attaching the arms of the mesh to the anterior and posterior vaginal walls, and attaching the other end (the tail) of the mesh to a ligament overlying the sacral promontory (the Anterior Longitudinal Ligament). The ASC is designed to make the full length of a woman's vagina available for sexual intercourse, should this be desired. Mesh implanted for abdominal sacrocolpopexy is passed into position via an abdominal incision and is not exposed to the native bacteria and other organisms in the vagina. Thus, the potential for microbial contamination of the ASC mesh is greatly lessened.

Mesh used as reinforcement in abdominal sacrocolpopexy is anchored in a vertical direction and is not attached to the muscles in the pelvis. When abdominally placed mesh shrinks during normal healing, this tends to result in a pulling up, or lengthening of the vagina, without the pain associated with pulling on skeletal muscle. For these reasons, the mesh placed for abdominal sacrocolpopexy behaves differently to, and cannot be compared with transvaginally implanted Prolift products.

In my opinion, transvaginal use of mesh in the "side-to-side" or side wall anchoring systems employed by the armed Prolift meshes is fraught with problems brought on by the design of the mesh and the use of the blind trocar passage system. The mesh is implanted transvaginally and the arms are passed through the levator ani, coccygeus, and obturator internus muscles, puncturing the muscles and pulling the polypropylene mesh arms through the muscle. This induces muscle pain and spasm. The arms are sharp and cut the muscle tissues as they are being pulled through and may damage nerves. This side to side fixation established by the implanted arms is a design feature of the meshes which creates non-anatomic mechanical stresses on the vagina and is an inappropriate design. As well, the devices are comprised, in whole or in part, of polypropylene.

The mechanical stresses imposed by the side to side attachment via the arms in combination with the shrinkage by the mesh cause patients to have pain. I have surgically removed transvaginally placed meshes from women who had complications related to previously placed Prolift transvaginal meshes. I have

personally observed shrunken, scarred explanted tissue and deformed Prolift mesh remnants as I have attempted to surgically remove the products.

It is my opinion that regardless of physician skill level, the complications induced by the "side-to-side" attachment of the arms into skeletal muscle, the shrinkage/contraction of the tissues and stiffening of the polypropylene will cause complications involving pain at rest, with movement, and with intercourse, pain and difficulty with defecation, coughing, movement, as well as obstructed voiding, and urinary incontinence. The mesh anchored transversely, side-wall to side-wall works against the natural mechanics of a woman's pelvis.

The complications that I have diagnosed and treated which are attributable to the design features, placement of the mesh and characteristics of the Prolift products include pain at rest and with coughing, jumping and straining, erosion, dyspareunia, constipation and defecatory pain and dysfunction, infections and abscesses, levator ani syndrome, de novo urinary dysfunction and deformation of the normal anatomy of the rectum and vagina.

The vagina is not a static organ. It functions as a support device; it stretches to accommodate its varied functions such as childbirth, intercourse, defecation and urination. The mesh is static and does not "give" according to the needs of the tissues in which it is implanted. Additionally, the fibrotic shrinkage further restricts the functional mobility of the pelvic floor organs and restricts the natural movements of the vagina during defecation, urination, and intercourse. These conditions cause pain.

To a reasonable degree of medical and scientific certainty, it is my professional medical opinion that the design defects and/or actions caused by the design defects cause and contribute to the pain experienced by women with transvaginal Prolift mesh implants.

TVT-Obturator (TVT-O) METHOD OF IMPLANTATION

For the Gynecare TVT-O sling, the IFU instructs the surgeon to use the "inside-out" approach. In this approach, the surgeon is instructed to mark the exit points of the sling tubes on the left and right thigh, lateral to the groin folds. Then, a 1 centimeter incision is made in the anterior vaginal wall under the urethra, 1 centimeter proximal to the urethral meatus. Blunt scissor dissection is then to be carried out under the vaginal mucosa at a 45 degree angle on the left and right. The mucosal dissection is carried to the body of the pubic bone, at the junction of the inferior pubic ramus. Then, an instrument called a "winged guide" is pushed through the dissected tunnel and into the obturator internus muscle. The winged guide is meant to be steer the sling through its course through the obturator internus muscle and groin tissues. The TVT-O sling comes enclosed in a plastic sheath, with each end of the sling fused to the sheath and a hollow plastic tube. The hollow plastic tube is threaded onto a curved needle, which is then passed through a groove in the winged guide, through the dissected vaginal tunnel, through the obturator internus muscle, and exiting on the skin of the inner thigh, lateral to the thigh folds, where the hollow tube is grasped and held with a clamp. Then the curved needle is withdrawn along with the winged guide, leaving the hollow plastic tube in its place of exit on the thigh

skin. The hollow tube is pulled out of the thigh incision until the sling and sheath become visible on the inner thigh skin. This method of passing the sling arms is performed on the left and right sides, such that the ends of the hollow tubes are protruding through the thigh skin on the left and right. The tape is then supposed to be placed loosely under the under the urethra by pulling on the ends exiting on the thigh skin on the left and right. Once the tape is placed, the plastic sheaths are pulled off of the sling material, and the sling arms are trimmed under the thigh skin. Then, the vaginal incision and obturator groin skin incisions are closed.

In summary, the TVT-O sling is pulled through the levator ani muscles, the obturator internus and externus muscles, the adductor muscles and the groin skin. The trans-obturator anchoring requires that the polypropylene be in contact with the vaginal wall over the course of its full width, increasing area of the scar plate formed during healing. Over time, the combination of mesh shrinkage and scar plate formation will cause the anchoring points to pull towards the midline, causing pain at rest, with sexual intercourse, and with movements that activate the pelvic floor, obturator, and usually the adductor muscles. Trigger points in the levator ani muscles, caused by the puncturing, shrinkage, and scarring of the trans-obturator sling, can cause spasm of the levator ani muscles, elevating and sharpening the anorectal junction, causing bowel evacuation difficulties and pain due to outlet obstruction from the more acute nonrelaxing anorectal angle.

Summary

As a fellowship trained specialist in Female Pelvic Medicine and Reconstructive Surgery, I have personally treated many women for complications related to transvaginal mesh repairs for pelvic organ prolapse and urinary incontinence. I am familiar with the medical complications that are generally associated with mesh repair surgery, and I am experienced in the recognition, diagnosis and treatment of patients suffering from complications caused by pelvic repair mesh implants. The most common mesh-related complications that I have personally seen are pelvic pain, pain with intercourse, pain with movement, pain with sitting, painful scarring of the vagina and pelvic floor muscles and tissues, painful scar bands or scar plates in the vagina, pain radiating into the groin, buttocks and thighs, paresthesias in the groin, buttocks and thighs, non-healing surgical scars, mesh exposure with odorous vaginal discharge, mesh erosion into the pelvic organs, vaginal shortening and strictures, chronic inflammation of tissue, wadding or bunching up of the mesh in the vagina, and nerve entrapment.

When I evaluate, diagnose, and treat women with mesh-related complications, I usually rely on an interview with the patient, review of her personally documented history, review of her medical records, and a detailed clinical examination when possible. I use the information that I obtain from these modalities to determine the cause, treatment plan, and prognosis for the patient's presenting complaint. The documents I reviewed related to Theresa England's case are attached as Exhibit 2.

Theresa England Chronology

Prior history
1988 – TAH LSO
2006 Cholecystectomy

11/4/2005 Cytology report (Vaginal walls)
Low grade SIL, with HPV effect

Plan
Colposcopy

12/1/2005 Pathology report
Specimen
Vaginal biopsy
Result
Chronic vaginitis with reactive changes
Early VAIN-I

4/21/2006 Office Visit (Dr. Yang)
Complaint
Presents for repeat pap smear
No abnormal symptoms
Denies bleeding
Denies pelvic pain
Status post Hysterectomy, Left salpingo-oopherectomy

Social History
Denies Tobacco use

Exam:
Enterocele
Grade 2 rectocele
Grade 2 cystocele
No Inguinal lymphadenopathy present

Assessment
Vaginal dysplasia
Rectocele
Enterocele
Cystocele

Plan
Pap completed (returned as LGSIL, VAIN-I)
Discussed Cervical Conization

10/26/2006 Office Visit (Dr. Yang)
Complaint
- Follow up VAIN I

ROS
- Denies
  - Urgency, Frequency, dysuria
  - Incontinence
  - Dyspareunia
  - Constipation

Exam
- No discharge
- No masses, rashes, or lesions
- Grade 1 Rectocele
- Grade 2 Cystocele
- Bladder nontender
- Urethra nontender
- No Inguinal lymphadenopathy present

Impression
- Vaginal dysplasia

Plan
- Pap taken
- Discussed incontinence and enterocele
- Follow up 6 months

11/3/2006 Office Visit (Dr. Yang)
Complaint
- 48 year old multipara
- Pelvic pressure and discomfort
- Urinary incontinence with
  - Coughing, laughing, sneezing

Exam
- Grade 2 rectocele
- Grade 3 cystocele
- Colposcopy
  - No distinct lesions seen
  - PAP returned as negative for SIL or malignancy

Assessment
- Cystocele
- Rectocele

Stress incontinence

Plan
- Anterior Prolift
- Rectocele repair with Gynemesh
- TVT
- Schedule Urodynamics
- Colposcopy performed
  - No definite areas of Dysplasia
  - No excision planned
- Risks discussed
  - Infection
  - Bleeding
  - Injury to organs
  - Anesthesia
  - Graft erosion
  - Recurrence of prolapse

11/14/2006 Procedure – Urodynamics
Results
- Calculated residual 225
- UPP 5
- No leak demonstrated
- Good compliance upon filling
- No Detrusor instability noted

11/22/2006: Procedure #1 (Dr. Yang)
Diagnosis
- Symptomatic third degree cystocele
- Second degree rectocele
- Urinary incontinence

Procedure
- Anterior Prolift rectocele repair
- TVT transobturator (TVT-O)
- Cystoscopy

Technique
- Anterior Prolift
  - Anterior vaginal wall injection with lidocaine with epi
  - Full thickness anterior vaginal wall incision
  - Anterior full thickness dissection to Arcus and apex
  - Cystoscopy performed
    - No bladder injury
  - Prolift assembled
    - Superficial incisions made

at the level of the urethra
deep incisions made
1 cm lateral, 2cm inferior to superficial incision
Guide placed into deep incision on right
Pushed thru groin incision, angled to ischial spine
Tip palpated, cannula advanced.
Loop retrieved and pulled out of deep incision
Clipped to drape
Superficial pass made on right
Loop retrieved, pulled out and and clipped to drape
Deep and superficial passes repeated on left,
Loops retrieved at superficial and deep locations
2-0 vicryl used to anchor the apex of the Prolift to the upper fascia
Deep passes pulled through cannulas first
Superficial passes pulled thru next
Prolift mesh laid flat, tacked anteriorly with Vicryl suture.
Cystoscopy performed
No injury
Mucosa closed with 3-0 monocryl
Prolift Mesh cinched to tension free under bladder
Cannulas removed
Excess mesh trimmed
Rectocele repair performed
Posterior dissection
Fascial defect closed
2-0 Vicryl figure of eight interrupteds
Mucosa closed with 3-0 monocryl

TVT-Obturator
Distal urethral incision made
Dissection carried to left, right
TVT -O placed
Wing guide placed
Trocar placed, exiting out superficial pass puncture
Tape pulled through on left, right, tension free under
Excess tape trimmed
Cystoscopy performed
No injury
Mucosa closed with 3-0 monocryl

Vaginal packing placed

11/29/2006 1 week Postop Visit (Dr. Yang)
Complaint
Feeling tired

Pain improving

Exam
No abnormal tenderness

Plan
Follow up 3 weeks

12/15/2006 4 week Postop Visit (Dr. Yang)
Complaint
Feeling something sharp sticking her near vaginal opening
No pelvic pain, fever or vaginal bleeding
Exam
No mesh exposure
Suture knot sticking out
Suture knot trimmed

Plan
Resume intercourse
Restart Premarin cream

12/28/2006 6 week Postop Visit (Dr. Yang)
Complaint
Voiding well
No pain
Sex not painful
Just some itching afterwards
Exam
Normal vault, no central or paravaginal defects
No discharge
Well healed
No mesh visible or palpable
Bladder nontender

Plan
Follow up 4 months

2/19/2009 annual gyn exam Visit (Dr. Glover)
Complaint
History of a kidney stone in summer 2007
Stent placed, stone passed
Complaining of intermittent left flank pain
Requesting CT to look for stone
Divorced

Exam
Absent uterus, cervix
Normal vaginal vault

Plan
Laboratory workup
CT scan ordered
Follow up annually

7/17/2010 annual gyn exam Visit (Dr. Glover)
Complaint
Hot flashes

Exam
Normal vaginal vault

Plan
Labs
Follow up 1 year

3/26/2014 gyn exam Visit (Dr. Halcomb) (8 years post Prolift/TVT-O implant)
Complaint
Vaginal dryness
Urinary urgency

Exam
Atrophic vaginal walls
Ridge effect anterior wall
Tender anterior wall with bleeding to speculum
Irregular surface and mesh palpable just below surface
Beginning to erode along mid suture line

Impression
Early vaginal erosion
Atrophic vaginitis
Urinary urgency

Plan
Vaginal estrogen
Follow up 3 months
If Estrace does not help urgency, consider bladder specific drugs.

12/3/2014 Office Visit (Dr. Halcomb)
Complaint
Using vaginal estrogen
Still having vaginal pain

Radiates to rectum
Still has pain with intercourse

Exam
Palpable mesh through anterior compartment wall
Palpable mesh through anterior compartment wall
Thick, tender ridge under bladder neck
No prolapse

Assessment
Pelvic pain
Mesh erosion
Atrophic vaginitis

Plan
Referral to Dr. Carl Zimmerman
Sent 12/4/2014

12/29/2014 Office Visit (Dr. Zimmerman)

Complaint
Vaginal pain
Lower abdominal pain
Dyspareunia
Urinary urgency

Medications
Lortab 10/325 for Migraines
Ibuprofen
Phenergan
Zofran
Estrace

Exam
Thickness/stiffness of the anterior vaginal wall
Tenderness in the right mid to apical anterior vaginal wall
Pinpoint exposure of Prolift material

Impression
Exposure/erosion of urogynecology graft material

Plan
Diagnostic cystoscopy
Revise the exposed area of mesh

1/20/2015 Procedure #2 (Dr. Zimmerman):

Diagnosis
Not given

Procedure
- Cystoscopy
- Removal of urogyn graft material
- Repair of cystotomy

Detail
- Cystoscopy
  - Patent ureters
  - Supratrigonal bunched mesh
    - seen under bladder mucosa, transcending mucosa
- Mesh excision
  - Anterior vaginal wall incision
  - Mesh dissected out
    - Attempt made to remove all available Prolift material
      - Deep, superficial lateral arms transected
    - Mesh was bunched
    - Mesh transcending bladder muscularis
    - Cystotomy occurred
      - Repaired with interrupted 4-0 Vicryl sutures
- Cystoscopy
  - Bilateral efflux seen
  - Bladder wall intact
- Vaginal wall closed with interrupted sutures

2/12/2015 Postop visit (Dr. Zimmerman)
3 weeks status post
- Cystoscopy
- Removal/revision of urogynecology graft material
- Repair of bladder injury due to mesh erosion

Complaint
- Bladder spasms

Exam
- Quarter sized granuloma bed in anterior wall
- Mesh filaments seen in apical right of the bed
- Bladder wall intact
- Tenderness in the area of healing to palpation

Impression
- Voiding normally
- Ongoing healing from full thickness removal of Prolift

Plan
- Continue Pyridium
- Finish antibiotic

Lortab #45 for pain

4/2/2015 Preop (Dr. Zimmerman)
Complaint
dry
Vaginal pain
Deep, central vaginal, persistent

Exam
Inflamed anterior vaginal wall
Mesh working its way to the surface

Assessment
Vaginal pain
Inflammation
Plan
MESH excision under anesthesia

4/22/2015 Procedure #3 (Dr. Zimmerman):
Diagnosis
Mesh exposure in vagina
Pelvic pain
Vaginal pain

Procedure
Excision of urogynecological mesh
Cystoscopy

Findings
2 cm area of mesh exposure in anterior vaginal wall
10 O'clock to 2 O'clock
Vigorous efflux from bilateral ureters
Permanent Suture at the level of the trigone
Urethra was intact

Detail
Cystoscopy performed
Mesh circumscribed with cautery
Vaginal flap containing mesh elevated, dissected from underlying tissue
Second area of mesh exposure elevated and dissected.
Exposed mesh was excised
Epithelium closed with 3-0 Vicryl in interrupted fashion
Foley drainage

5/1/2015
Postop Visit (Dr. Adam)

9 days post mesh excision
Foley removed 4/27 with normal void noted

Complaint
- Significant urinary leakage since last night
- Increasing suprapubic pain
- Severe nocturnal enuresis last night
- Insensible urine leaks throught the day

Exam
- Copious amounts of urine in the vaginal vault
- Urine leaking from vaginal suture line

Impression
- Vesicovaginal fistula

Plan
- Continuous catheterization for 3 weeks
- Office cystoscopy
- Consider operative intervention if no relief

5/6/2015 Procedure #4 (Dr. Adam):
Diagnosis
- Vesicovaginal fistula

Procedure
- Cystourethroscopy

Findings
- Normal urethral mucosa
- Normal bladder neck coaptation
- Moderate sized vesicovaginal fistula (1 centimeter)
  - Just above interureteric ridge
  - 1 centimeter from right ureteric orifice
- Possible mesh erosion into trigone
- Normal ureteric efflux
- Area of small mesh erosion at 1 O'clock to right UO

Impression
- Supratrigonal vesicovaginal fistula

Plan
- Vesicovaginal fistula repair

5/12/2015 CT Abdomen/Pelvis

Findings
- Vesicovaginal fistula from posterior urinary bladder
- Cholecystectomy and hysterectomy noted
- Normal right ovary
- Left ovary not seen

5/14/2015 Procedure #5 (Dr. Adam):

Diagnosis
- Vesicovaginal fistula
  - Supratrigonal, close to right ureteric orifice
- Vaginal Mesh complication
  - Mesh erosion

Procedure
- Exploratory Laparotomy
- Cystoscopy with bilateral ureteric catheterization
- Vesicovaginal fistula repair with omental flap
- Vaginal and bladder mesh excision
- Right ureteroneocystotomy
  - Placement of right ureteric double-J stent

Findings
- Cystoscopy
  - 1 cm supratrigonal fistula, just to the right of midline
    - Near right ureteric orifice
  - Mesh visualized
    - In the trigone
    - Bunched up mesh on the right within detrusor muscle
      - Adjacent to right ureter
- Cystotomy repair watertight at the end of the case

Technique
- Ureteral catheters placed
  - Right placed over glidewire
  - Left placed uneventfully
- Supratrigonal fistula visualized
- Midline vertical abdominal incision made
- Peritoneum entered sharply
- Bookwalter retraction
- Fistula repair
  - Bladder mobilized
  - Retropubic space developed
  - Bladder opened in clamshell fashion
  - Fistula located
    - 1 cm from right ureteric orifice
    - 1.5 cm away from left ureteric orifice

Fistula tract removed with care taken to avoid ureters
Sheet of mesh seen in detrusor muscle on the right
Mesh dissected off detrusor and vaginal epithelium
1 x 2 centimeter piece of mesh excised on right
Vaginal epithelium mobilized for bladder closure
Small piece of mesh excised from left side
Vaginal epithelium mobilized to left and distal to fistula
Vaginal epithelium closed with 3-0 interrupted Vicryl
Bladder closed with 4-0 interrupted Vicryl
Mesh palpable on right, close to ureter
Right ureter re-implanted
Bowel re-packed
Right ureter mobilized, stent removed
Distal ureter tied off
Ureter transected
Neocystotomy made at right bladder come
Away from fistula
Ureter brought into neocystotomy and spatulated
no tension
ureter sutured to bladder mucosa with five 4-0 vicryl sutures
glidewire and pigtail catheter placed in right ureter
to 24 centimeters.
Glidewire removed
Left ureteric stent removed
Foley changed to 3 way Foley
Cystotomy repair was continued
Posterior to anterior
Running 3-0 Vicryl
Suprapubic catheter placed prior to completing closure
Second layer of running 2-0 Vicryl
Bladder instilled with water
No leakage
JP drain brought placed in posterior culdesac
Omentum brought down
tacked into place in vesicovaginal space
Closure
Fascia
Deep tissues
Skin

6/12/2015 Postop Visit (Dr. Adam)
Complaint
Urinary leakage
Believes it was transurethral

Bladder spasms after being physically active
Currently on Oxybutynin ER

Medications
Phenergan
Zofran
Ventolin
Colace
Oxycodone-acetominaphen
Vesicare
Nitrofurantoin

Exam
No evidence of recurrent vesicovaginal fistula
Evidence of adequate healing so far
Unable to remove suprapubic tube in the office

Plan
Exam under anesthesia
Cystoscopy
Suprapubic catheter removal
Stent removal

6/1/2015 Procedure #6 (Dr. Adam):
Diagnosis
Unable to remove Suprapubic tube in office

Procedure
Exam under anesthesia
Suprapubic catheter removal
Ureteric stent replacement

12/20/2016 Procedure #7 (Dr. Adam):
Diagnosis
Vesicovaginal fistula
recurrent

Procedure
Closure vesicovaginal fistula, vaginal approach
Left ureteral stent placement
Under fluoro guidance
Findings
2 fistula tracts
3 mm fistula tract at trigone
On left near ureteric orifice
3 mm tract at bladder neck

Technique
- Fistula tracts cannulated
- U shaped incision on anterior vaginal wall
- Both fistula tracts isolated
- Left ureteric double J stent placed to aid fistula excision
- Fistula tracts excised together
  - 1-centimeter cystotomy remained after fistula tract excisions
- Fistula tract closed with
  - running 4-0 PDS
  - imbricated with interrupted 3-0 Vicryl
  - left ureteric orifice seen 8-9 mm away from closure area
- Bladder instilled with irrigation via Foley
  - Completely watertight closure noted
- Vaginal incision closed with interrupted 2-0 Vicryl

Postoperative Pelvic Floor symptoms

New symptoms/problems since Prolift/TVT-O procedure
- Urinary retention
- Fistula
- Mesh erosion into bladder , vagina
- Recurrent vaginal/pelvic pain, onset 2014.
  - Radiates down legs
- Frequent rectal and sacrum pain
- Rectocele
- Dyspareunia

Theresa England underwent a Gynecare anterior Prolift, and Trans-Obturator sling procedure in 2006 to address her cystocele and stress urinary incontinence. Following that surgery, she developed vaginal dryness, urinary urgency, vaginal pain, pelvic pain, and pain with sexual intercourse. These bothersome symptoms caused her to seek additional care, and she was evaluated and diagnosed with an erosion of the mesh into her vagina with bleeding, and a tender, anterior wall spanning foreign body. She was referred to a gynecologic surgeon, and she was offered partial excision of the eroded transvaginal mesh. She

underwent a partial anterior mesh excision, and the anterior mesh was found to be bunched up, and deeply embedded in the detrusor muscle. She sustained a bladder perforation during the excision of the deeply embedded Gynecare mesh, and this cystotomy was repaired during the surgical procedure.

Theresa England developed bladder spasms along with persistence of her pelvic and vaginal pain following the partial explantation procedure. On evaluation, she was found to have persistent granulation tissue, along with tenderness and additional mesh erosion in the anterior vaginal wall. The underwent a second attempt to remove portions of her anterior transvaginal mesh, and a 2 centimeter area of eroded vaginal mesh was found in and excised from the anterior vaginal wall.

Following this second attempt at mesh explantation, Ms. England complained of persistent vaginal leakage, and was found to have a vesicovaginal fistula, unresponsive to prolonged bladder catheterization. She was evaluated by a urogynecologist, and was found to have a supra-trigonal fistula, and erosion of the anterior wall mesh into her bladder below the trigons. She then underwent a 4th surgical procedure by a urogynecologist cystoscopically map the fistula, and a 5th surgical procedure to explant sections of the eroded bladder mesh, and close the vesicovaginal fistula, along with right ureteral reimplantation due to close involvement of the right ureter with the fistula and eroded mesh in the bladder. Theresa England continued to have bladder spasms and vaginal leakage. She was evaluated and diagnosed with recurrent vesicovaginal fistulae at the bladder neck and at the left of the bladder near the ureteric orifice. She underwent a 6th procedure to close the complex vesicovaginal fistula via the transvaginal route. All

told, in addition to the Gynecare Prolife and TVT-O procedures, Theresa England required 5 additional surgical interventions in order to address complications caused by the Gynecare Prolift and TVT-O mesh devices.

Despite these 5 additional surgical interventions, Theresa England complains of vaginal pain, pelvic pain, and pain with attempts at intercourse. She did not have any of these symptoms before implantation of the Gynecare Prolift and TVT-O transvaginal mesh products.

Theresa England had vaginal vault prolapse and stress urinary incontinence before implantation of the Gynecare Prolift and TVT-Obturator sling. She did not have chronic pelvic pain, pain with intercourse, or a fistulous tract between her bladder and vagina.

In the thirteen years after her combined Gynecare Prolift and TVT-Obturator surgery, Theresa England required 5 additional surgical interventions to address complications caused by the Gynecare Prolift and TVT-Obturator mesh products

Despite 3 mesh revision attempts, a diagnostic cystoscopy, and an additional surgery to address a residual vesicovaginal fistula, Theresa England continues to have vaginal pain, pain with intercourse, chronic constipation, and pelvic pain.

Despite the 3 revision attempts, Theresa England still has the arms of the Gynecare Prolift and TVT-Obturator sling embedded and scarred into her groins and paravaginal tissues on both sides of her body. Specifically, she still has six arms of the Gynecare mesh products remaining in her groin and paravaginal tissues; 2 arms from the TVT-O, and 4 arms from the anterior Prolift mesh product. The prognosis for these 6 remaining arms is unknown.

Differential Diagnosis

In determining the cause of a specific injury, the process of "differential diagnosis" is applied to identify potential causes of the injury, and then by process of elimination, to "rule out" the least likely causes to arrive at the most likely cause. This process of differential diagnosis, or differential etiology, is a well-established and universally accepted methodology for determining the cause of injuries employed by physicians throughout the United States. I have used that methodology in arriving at my opinions in this case.

Prior to her Gynecare Prolift and TVT-Obturator surgery, Theresa England had a history of abdominal hysterectomy, removal of one ovary, vaginal Intraepithelial Neoplasia (VAIN), and cholecystectomy. She was a never smoker, who denied urinary frequency/urgency, dyspareunia, or constipation.

None of her pre-existing conditions or surgeries involved the placement of synthetic mesh into the vagina. None of the above conditions are recognized as being risk factors for mesh erosion into the vagina or bladder, chronic pelvic pain, pain with intercourse, or constipation.

Without mesh implantation, there can be no mesh erosion. Theresa England's bladder erosion, which caused her vesicovaginal fistula, and vaginal mesh erosion were directly caused by the Gynecare Prolift and TVT-O mesh devices.

Theresa England's complaints of chronic pelvic pain, vaginal, and pain with intercourse, began after implantation of the Gynecare Prolift and TVT-O mesh devices. The mesh arms punctured, and scarred into the levator ani, obturator and

adductor muscles and groin tissues, and then shrunk, placing painful traction on the pelvic, groin, and leg muscles and tissues. This scarring and shrinkage of the mesh into the muscle causes muscle spasms and pain at rest, which is made worse when the muscles are touched (as they would be during sexual penetration), or when the muscles are mobilized during attempts to walk, climb stairs, or exit from a car. More likely than not, this scarring and contraction of the Prolift and TVT-O Arms is the only cause of Theresa England's vaginal pain, and also her pain with sexual intercourse. These pain symptoms are therefore directly attributable to the placement of the Gynecare Prolift and TVT-O mesh sling arms into the pelvic floor and obturator muscles because there is no other credible explanation.

Furthermore, the scarring of the Gynecare Prolift and TVT-O mesh arms into the levator ani, followed by mesh contraction and pulling on the levator muscle caused spasm and contraction of the pelvic floor muscles, causing outlet constipation due to sharpening of the anorectal angle.

Theresa England has no other significant risk factors for her vaginal pain, pelvic pain, dyspareunia, or vesicovaginal fistula This leaves the Gynecare anterior Prolift and TVT-Obturator sling as the only cause of Theresa England's debilitating pelvic floor symptoms.

Theresa England required multiple additional attempts to remove the vaginal portion of her anterior Prolift and TVT-Obturator sling arms, but the arms of the sling remain embedded and scarred into her left and right groins and are more likely than not contributing to her pain. Specifically, Theresa England still has six

arms of the Gynecare mesh products remaining in her groin and paravaginal tissues, 2 arms from the TVT-O, and 4 arms from the anterior Prolift mesh product.

I have personally seen women like Theresa England with chronic vaginal and pelvic pain caused by the remaining arms of partially explanted Prolift and TVT-Obturator type slings. I have personally seen that, because of the presence of the scarred in mesh arms, these women cannot be cured with physical therapy alone, but require complete explantation of the embedded mesh arms before physical therapy can be successful in releasing the muscle spasm caused by the scarring from the mesh.

In my surgical experience, anterior Prolift and Trans-Obturator mesh complications like those seen in Theresa England are difficult to treat, and complete removal of the scarred-in mesh remnants represents a significant surgical challenge, which carries risks of blood loss, as well as nerve and urinary system damage, and substantial scarring of the vaginal and groin tissues.

Theresa England's Gynecare Prolift and TVT-Obturator implantation was performed using acceptable surgical practice, and in accordance with the Gynecare TVT-Obturator and Prolift IFUs. In my opinion, her chronic pelvic pain and dyspareunia occurred because of the scarring of the of the Gynecare Prolift and TVT-Obturator mesh into the anterior vaginal wall and pelvic floor, obturator, and groin tissues, followed by post implantation contraction of the Prolift and TVT-Obturator meshes, which placed traction on the pelvic floor, obturator, and groin muscles and tissues. Her bladder and vaginal mesh erosion are directly caused by the implantation of the Gynecare and Prolift mesh devices.

These complications experienced by Ms. England from her Gynecare anterior Prolift and TVT-Obturator vaginal mesh are similar to complications that I have personally seen in other women who have come to me for treatment of chronic painful, contracted Prolift mesh and TVT-Obturator sling devices.

Like Theresa England, many of these affected women require multiple surgical and other therapeutic interventions in order to improve their symptoms to a level that they are able to live with. Despite multiple surgical, medication, and physical therapy interventions, some of these women will never be cured of their mesh induced symptoms.

Opinion:

So far, in addition to the anterior Prolift and TVT-O sling implantation surgery, Theresa England has required 6 additional surgeries to address complications caused by her anterior Prolift mesh and TVT-Obturator Sling. Ms. England still has sling mesh arms remaining in her groin and paravaginal tissues on her left and right sides. Theresa England's mesh complications of bladder and vaginal erosion would not have occurred with a native tissue repair like a Burch colposuspension or autologous fascial retropubic sling, or the anterior repair with uterosacral suspension or sacrospinous fixation to address her prolapse.

Theresa England's vaginal pain, dyspareunia and constipation due to levator spasm would not have occurred with a retropubic synthetic sling because the retropubic sling arms do not puncture and scar into the levator ani muscles causing pain.

Ms. England's dyspareunia, and vaginal pain would not have occurred with a laparoscopic sacrocolpopexy, in which the abdominally placed, synthetic mesh attaches to the anterior/posterior vaginal walls and vertically to the sacral promontory, avoiding the levator ani, obturator, and adductor muscles thereby removing opportunities for causing vaginal, or groin pain. Furthermore, in the highly unlikely event of a mesh erosion or complication with the retropubic synthetic sling or sacrocolpopexy, the retropubic sling and/or the sacrocolpopexy mesh can be completely explanted laparoscopically or robotically under direct visualization in a single surgical intervention.

In my opinion, the prognosis for Ms. England's persistent, chronic dyspareunia, pelvic pain, and constipation, is uncertain. This is because the vaginal scarring caused by the mesh placement, and the 3 explantation surgeries that she endured, will make subsequent repairs more difficult and less likely to be effective.

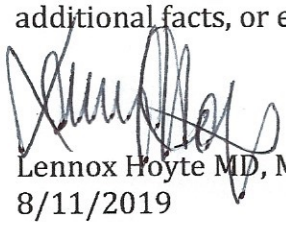
As far as Theresa England's chronic pelvic pain, and pain with intercourse is concerned, she has not had relief from a course of vaginal estrogen. This makes vaginal atrophy an unlikely cause of her dyspareunia. It is more likely than not that her pain with intercourse and her vaginal pain are due to the vaginal wall scarring , and pelvic muscle spasms caused by her Gynecare Prolift and TVT-Obturator devices, and her subsequent surgeries to remove the spanning mesh and repair her recurrent fistulas.

Theresa England did not complain of constipation before her Gynecare Prolift and TVT-Obturator surgery. She did not have pelvic floor dysfunction before her Gynecare Prolift and TVT-Obturator mesh implantations. As noted elsewhere in this report, more likely than not, Theresa England's constipation is therefore caused by painful spasm of the levator ani muscles, which sharpens the anorectal angle, causing her difficulties with stool evacuation. This spasm is directly caused by the painful scarring of the levator ani muscles caused by the passage and scarring in of the Gynecare Prolift and TVT-Obturator sling arms. In the absence of a persistent source of pain (ie., the Prolift and TVT sling arms), this kind of levator spasm is treatable with myofascial release pelvic floor physical therapy. This leaves the painful scarring of the levator ani muscles caused by the passage of the Gynecare Prolift and TVT-Obturator sling as the only remaining cause of Theresa England's chronic constipation.

The Gynecare TVT-Obturator IFU does not appropriately disclose the risks of these products. A patient cannot adequately give informed consent unless they are given all of the medical facts accurately by their physician to have an adequate picture of the risk profile they are consenting to. The physician cannot adequately give them all of the necessary information unless it is provided by the manufacturer in the IFU. The manufacturer of a permanent medical device implant is in the best position to know all of the short- and long-term risks and must disclose all of the risks known to it and give a fair depiction of the risk profile of the device. Gynecare failed to warn physicians and patients about numerous complications it knew or should have known, including the following: Chronic pain, groin pain, chronic

risks known to it and give a fair depiction of the risk profile of the device. Gynecare failed to warn physicians and patients about numerous complications it knew or should have known, including the following: Chronic pain, groin pain, chronic dyspareunia that may never resolve, need for multiple revision surgeries to address bothersome mesh related symptoms, inability to remove all of the mesh, mesh shrinkage, painful scar plate formation, mesh contraction, urinary and fecal dysfunction, and reduced efficacy of future SUI procedures.

All of my opinions are made to a reasonable degree of medical certainty. I reserve the right to amend or supplement these opinions based on new information, additional facts, or examination findings.



Lennox Hoyte MD, MSEECS
8/11/2019